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INTRODUCTION

This document has been developed to assist you in performing your work on Pfizer Corporation premises. It provides you with an overview of specific procedures to be followed while working at any of our Kalamazoo area sites. Applicable federal, state, or local laws, and Pfizer procedures, policies and practices shall apply to all contract work. Willful disregard of any of the laws or policies cited will be cause for indefinite badge revocation and removal from the premises.

DEFINITIONS

1. Supplier:

A supplier is a non-Pfizer business entity (including independent contractors) under contract to provide individuals to perform specified services or results on a temporary or long-term basis. The firm will be responsible for the performance and status of its workers as well as any and all employer related obligations, regulations and laws.

2. Contractor:

A Contractor is an individual employed by a Supplier to perform specified services within Pfizer to support business operations, specific projects or tasks.

3. Pfizer Contact

The Pfizer Contact is a Pfizer employee who, through appropriate delegation of authority, is operationally administering the business agreement (contract) with an outside firm or independent contractor for specified services or results. The Pfizer Contact will be the ongoing liaison should questions/issues arise.

4. Kalamazoo Contractor Administration

The Pfizer Kalamazoo Contractor Administration (KCA) group is responsible for the management of contractor activities at all Kalamazoo sites. The activities are divided into two distinct areas of responsibility.

1. KCA is responsible for moving contractors through the contractor badging process. This is to ensure accurate headcount reporting of all contractors. These activities include:
   • Ensuring a contract is in place with the supplier firm (contractor and subcontractor)
   • New (first time on a Kalamazoo Site) Contractor badging process referred to as “onboarding”
   • Maintaining the Pfoenix contractor management software system.
- Management of Pfizer asset use by contractors.
- Management of the removal of existing contractors referred to as “offboarding”
- Management of Annual Renewal of existing contractor Orientation training

2. The KCA group also has responsibility for enforcement of all EHS/OSHA regulations for the Contractor workforce. It is very important that contractor work is conducted in a safe and environmentally sound manner. There are numerous Environmental, Safety, and Health policies that apply to the many different types of contractor work on site. Those policies are contained in the Contractor Environment Health and Safety Manual. The manual is intended to be a concise breakdown of the site policies, so that contractors can determine if a policy, or program, applies to their particular work. KCA will assist in determining which policies and programs apply. However, contractors will still be responsible for assuring that all applicable programs and policies are followed.

Paper copies of this manual may be obtained at:

http://pgmkzo.pfizer.com/kzoeng/ConMgmt/Orientation.htm

GENERAL INFORMATION

1. Company Access

Access badges must be obtained prior to beginning work at Pfizer. Badges must be visibly worn at all times while on the premises and must NOT be traded or shared with other workers.

These badges are the property of Pfizer and must be returned to Security upon completion of the job. A lost badge must be reported immediately to your Pfizer Contact, who will notify Security.

Pfizer will be closed to contractors on weekends and certain holidays unless approved in advance by the Pfizer Contact. Your Pfizer Contact will arrange with Pfizer Security for nonstandard/holiday access.

2. Vehicle Admittance & Parking

All vehicles parked on Pfizer premises must display a Vehicle Identification Card in the driver's side windshield to identify the owners of private vehicles in case of an emergency. These cards will be distributed with contractor’s badges. Contractors will park personal vehicles in designated parking areas only. Do not park in reserved, handicap spaces, on roadways or sidewalks, service drives near doorways, loading docks, dumpsters, or in an access route to or near fire hydrants. Specific parking designations are as follows:
Version 1.0, Effective January 1, 2007 Page 6 of 26 Portage East Complex: Several options are available for contractor parking on the Portage East site depending on the location of the work being performed. Contractors are generally expected to park personal vehicles outside fenced areas unless they have a valid permit. General parking is available in the contractors lot east of Guardhouse #1 (off Romence Parkway) or in the outer rows of the northwest corner lot (southeast corner of Romence Parkway and Portage Road). Vehicles needing access to the fenced area will be issued special permits. Authorized vehicles accessing the fenced area during normal working hours must use the entrances at Guardhouse #1 (Romence Parkway) or Guardhouse #3 (off Portage Road). Access to the site other than normal working hours (1800 to 0600 hours) is to be through Guardhouse #1 only. Permission must be obtained from your Pfizer Contact and Plant Security prior to access during non-standard hours (1800 – 600 hours).

Downtown Research and Development Site: The Pfizer Contact or the Construction Manager will arrange parking for all downtown contractors. Access to the fenced area at the corner of Portage and Lovell Streets is by card key access and must be approved /arranged by the Pfizer Contact.

Richland Farm Site: The entrance to the Richland Animal Health Site is located on 28th Street. Contractors should park in designated areas near where they will be working with travel on the farm roads limited to what is necessary to get to and from the job. Contractor vehicles should not be on farm lanes or field access roads unless work activities require them to do so.

3. Tobacco Products

Use of tobacco products of any kind are prohibited inside any Pfizer building or inside the fenced areas of the Portage East facility. Your Pfizer Contact will inform you of designated smoking locations for the facility at which you are working, as they vary from site to site throughout the Kalamazoo campuses.

4. Cafeterias and Snack Bars

Designated cafeterias and snack bars are open to contractors. Contractors are expected to use the cafeterias and snack bars only during regular service hours. Your Pfizer Contact will inform you of these restrictions. Proper attire and a reasonable level of cleanliness are expected while in Pfizer cafeterias and snack bars.

5. The Federal Food, Drug and Cosmetic Act

The United States Government enacted legislation that regulates the pharmaceutical industry. These laws and regulations protect the public from companies who make and sell drug products using unlawful methods and under less than sanitary conditions. These laws apply to Pfizer employees and contractors who work at a facility such as Kalamazoo. Anyone working at a Pfizer site must be trained about these regulations, and how you impact product quality through your actions, or inactions. Your Pfizer contact is responsible for arranging required on-the-job training or job-site training.
The consequences of not following the laws and regulations are significant. Food and Drug Administration Investigators are authorized to inspect Pfizer facilities. Investigators may find violations that can result in consequences that include: jail time, plant closure, fines, product recalls, patients going without their life saving medicines or patients receiving adulterated medications.

Any individual found to have intentionally engaged in fraud or product adulteration can be held criminally liable under the Food, Drug, & Cosmetic Act.

6. Good Manufacturing Practices (GMP) or Good Laboratory Practices (GLP)

GMP and GLP are manufacturing and research practices that are in place to prevent patients from getting adulterated drugs. This Food Drug and Cosmetic Act requires that we follow GMP’s and or GLP’s.

Good Manufacturing Practices/Good Laboratory Practices are found in the U.S. Government document called the Code of Federal Regulations (CFR). Certain parts of the CFR are translated into specific Pfizer procedures, or Standard Operating Procedures (SOPs), or Reference Instructions (RIs). These documents describe processes used in the manufacturing, processing, packaging, or holding of drugs. They have a formal approval process and a method for keeping them up to date. By following the procedures in those documents exactly, without exception, we assure the Food & Drug Administration (FDA) that we follow Good Manufacturing Practices and or Good Laboratory Practices.

By following SOP’s and RI’s consistently, Pfizer assures that our drug products are made with high quality and that they are the correct strength, purity, identity and efficacy. As contract employees working in or around Pfizer facilities, Pfizer expects that SOP’s and RI’s will be followed to ensure your health, and to protect the product and processes you are working around from contamination.

Your Pfizer contact or their authorized Pfizer designee is responsible for seeing to it the SOP’s and RI’s are made available to you, and training is provided prior to working on a job!

7. The Importance of Training

The Code of Federal Regulations states the each person who works in a GMP facility shall have the education, training and experience to enable him to perform his assigned job function. Training will focus on the particular operations that the employee performs and include current Good Manufacturing Practices related to their job function. Therefore, you
Your Pfizer contact is responsible to assure that you receive the proper on-the-job training or work site training so you can perform your job in accordance with GMP’s or GLP’s related to your job function.

A positive attitude toward training is important. When you will be actively involved in training sessions and apply the training on the job as required, Pfizer can be assured the task will be completed safely and efficiently.

Upon completion of classroom style training you are required to print your name, write your signature, date and name of your employer on a Training Sign-in Sheet. The Training Sign-in Sheet provides Pfizer and the FDA with documentation of the required training. You may also be asked to document other on-the-job training by signing other types of training documentation forms.

8. The Importance of Documentation

The Code of Federal Regulations states that if you didn’t document it, you didn’t do the work, or take the training session.

GMP and GLP regulations require that we document our work. As a contractor or service provider your work, or training, is documented by you printing your name, providing your signature, list the date of the work you performed and the name of the employer you work for. When documenting these things do the following:

• Write clearly and use black ink only.
• When making entries into work logs, do it immediately after the work activity occurs.
• Fill in all blanks required; do not leave blank lines. Write N/A if needed.
• Line out mistakes or incorrect entries, write the corrected information, write your initials next to the corrected entry, and the date on which the corrected data was written down. Do not erase, use white out, or cross out the incorrect data to the point where it can’t be recognized as it was originally written.
9. Employee and Product Protection

Because people are the biggest source of contamination in our work site, GMP and GLP regulations include requirements to prevent contamination to our products and processes used to make, hold, test or distribute our drugs. To prevent contamination Pfizer monitors the hygiene practices of people, the flow of people traffic in the site, restricted access in various areas, and housekeeping or cleanliness of the workplace.

A. Housekeeping and Cleanliness of the Workplace- physical contamination

Examples of physical contamination are tools or materials that make their way into raw materials or product. Material or foreign objects left in equipment may dissolve in the process and become a chemical contaminant (a tape measure or gasket that dissolves in the process solvent). Product or materials contaminated in this manner may need to be destroyed.
Examples of activities to be aware of to promote Pfizer product safety are:

- **Tool control:** Make sure all of your tools are accounted for when you finish a job.
- **Certain waste containers are specifically for product waste and can’t be used for general garbage.** Be alert to labels on waste containers.
- **Teflon tape:** Begin applying tape on the second thread and back from the end of the pipe. Teflon tape should not be exposed or come into contact with drug substances, additives or production processes.
- **Pipe dope:** Adhere to all Pfizer Piping standards.
- **Gaskets that come with equipment should be checked with the operating unit to make sure that they are the correct ones.**

Contractors are held accountable for littering and tool control when it contributes to unsafe or unsanitary housekeeping conditions on the job site.

**B. Pedestrian Traffic and Restricted Area Access at Pfizer**

When entering a Pfizer facility, all contractors must be alert to the signs posted at entrances that restrict access to people. Some areas require extremely clean conditions in the air and on surfaces. Only highly trained individuals are allowed to enter these areas. Each area has different access restrictions. Your Pfizer contact or the Operations Unit can inform you of specific dress requirements that may affect your work.

Signs are used to inform contractors which type of head covers, uniforms, beard coverings and foot covers that must be worn in a given area. Restricted access protects all contractors, employees, animals and pharmaceutical products from contamination from hair, fibers, skin cells, dust, dirt, vermin, germs and bugs. One of the ways to control contamination from insects and pests is accomplished by limiting where people consume food and drinks.

Consumption of any kind of food or drink other than water is allowed only in building cafeterias, snack bars, or other designated areas. Here are a few other restrictions that help maintain an environment free of contaminants in a GMP or GLP facility like Pfizer:

- No beverages are to be carried from an employee’s vehicle to their work place inside the fenced area of the Portage East Complex.
- Absolutely NO toothpicks, food, including gum, candy, snacks, or drinks are allowed in the manufacturing areas, or laboratories.
- Live plants are prohibited in manufacturing areas and buildings. Plants and soils can harbor many life forms (insects or microorganisms) that can be a source of product contaminates.
- Doors and windows must not be propped open under any circumstances, unless approved in advance by your Pfizer Contact.
C. Hygiene Practices of Contractors

It is expected that contractors will practice good personal hygiene and wear clean clothing that is appropriate for the job and the work area. In some restricted manufacturing areas, and/or research areas, contractors are expected to wear hairnets, beard covers, shoe covers, and tyvek suits covering your clothing.

Cosmetics, artificial nails, jewelry, watches or wedding rings with stones may not be allowed. Be sure to follow the specific policies and SOPs for the area you will be working in.

All contractors must report wounds and illnesses to their Pfizer Contact. Open lesions can impact product quality in areas with restricted access and controlled environments.

10. Security

Pfizer has made a substantial investment in its people, facilities, and equipment. Our Security Services Team is charged with protecting those important resources. Pfizer has a staff of security professionals who concentrate on site protection. This task can be done much more effectively with your help. By following a few simple security rules, contractors can ensure that Pfizer’s investment, as well as your Company’s people and property, receive the best protection:

Be ready to show your Contractor Badge - We can best protect our site by controlling who has access to it. Security Officers may ask to see your contractor badge when you enter a site, or building. Remember - they are doing their job. A “spot check” means they are checking to see if you are authorized on the site.

Wear your issued Contractor Badge – If you work in an area that is specifically identified as a GMP area, you must wear your badge below the waist. Everyone must always display their contractor badge prominently, and always on an outer garment.

Don’t lend your Contractor Badge to anyone or use an access badge to let others into locked areas – Many areas at Pfizer are protected by automated card access readers. Do not enter these areas unless YOUR access card lets you in. One very important piece of information -- using someone else’s contractor badge, or lending yours to someone, WILL result in you being asked to leave the premises.

Lock up your property - Pfizer cannot be responsible for the security of personal items or contractor equipment. If your equipment will be stored on the site overnight, please consult your Pfizer contact concerning an appropriate, secure storage area.

All items are subject to search - In order to protect the site properly, Pfizer reserves the right to inspect all vehicles, packages, bags, and other effects coming into, leaving the site, or while they remain on Company property. Be sure you check with your Pfizer Contact before bringing any questionable items onto the work site.
Report any suspicious activities - Don’t hesitate to report any suspicious activity to Security or to a Pfizer employee. The Security Team would rather respond to a false alarm, than investigate a serious theft or incident.

11. Substance Abuse Program

Contractors must participate in their Supplier’s approved substance abuse program that must include pre-employment/pre-access, for cause, random and accidental injury testing as defined by Pfizer’s substance abuse policy.

12. Prohibited Activities

The following activities, most of which constitute gross misconduct, are strictly prohibited on Pfizer property:

A. Possessing or using alcohol or illegal substances, or reporting to work while under the influence of either

B. Gambling or playing of games for money

C. Bringing weapons, firearms, ammunition, or incendiary devices on site or being in possession of such devices on company time

D. At the Portage site, using cameras, or taking pictures on cell phones with picture taking capabilities, without written approval of site management. Requests for photographs at the Richland Farms or the Downtown Kalamazoo Site must be approved by site management.

E. Duplicating, destroying, or copying Pfizer records, or removing such records from the property

F. Horseplay

G. Sexual harassment, including unwelcome sexual advances and other behavior which interferes with another's work performance or creates an intimidating, hostile, or offensive work environment

H. Stealing or pilfering from Pfizer, a Contracting Firm, or an individual

I. Using individual radios, earphones, tape recorders, etc.

J. Use of tobacco products in buildings and inside the fence surrounding the Portage Chemical and Pharmaceutical Manufacturing areas
K. Collecting contributions, vending, soliciting, distributing notices, handbills, posters, or any other written or printed material for any purpose while on the Pfizer work site

L. Fighting

M. Unauthorized personal electronic devices (cellular phones, personal pagers, etc.) are prohibited in many production areas. Cell phones, personal pagers, and/or Personal Data Assistants (Palm Pilots, etc.) that are not designated as intrinsically safe, are not allowed in some areas, and may be confiscated.

13. Special Considerations for Research and Development and Richland Farm Areas

If your work requires you to enter research areas either at the downtown campus or the veterinary research complex in Richland, Michigan there are unusual circumstances you may encounter. You may see animals in cages, laboratory viral and bacteriological studies that use growth media, and studies that use syringes and other equipment that you may not be familiar with. Special permission must be obtained before you enter any area that is designated as RESTRICTED. You must check with your Pfizer contact, or Pfizer Facility Management about special gowning, shower in and shower out procedures, and follow all Personal Protective Equipment (PPE) before you may enter these areas.

HEALTH & SAFETY

Note: Pfizer Kalamazoo EH&S Department publishes an Emergency Procedures Handbook. The handbook may be picked up when the contractor receives their badge. Contractors should use this book as a reference and be familiar with the procedures contained in it.

1. Emergency Reporting Procedure

In the event of a FIRE, activate the nearest fire alarm, then dial 1-2-3 on any Kalamazoo Site company phone or dial 833-4799 on any of the non-company, or cell phone(s) throughout the Kalamazoo Site. Some sites in Kalamazoo have telephones that are RED. They will connect you to the Pfizer Fire Station.

In case of a Medical Emergency or Chemical Spill, dial 1-2-3, as directed for a fire.

When speaking with the Pfizer dispatcher remember to:

A. Stay CALM and speak clearly.
B. Give your name, the phone number you are calling from, the building, floor number and room number, if known (also department and unit number), the type of emergency and any other information requested.

C. Do NOT hang up until told to do so. Allow the dispatcher to ask questions and guide the conversation.

D. Notify your Pfizer Contact as soon as possible.

2. Injury Reporting Procedure

Because any incident is potentially serious, it is Pfizer policy that all injuries be promptly reported and investigated. Contractor injuries are to be reported to your supervisor who will contact Kalamazoo Contractor Administration to begin the investigation process.

Any injury involving chemical exposures should be directed to the Pfizer KCA group, or call 1-2-3. Any emergency medical issue (those that require ambulance transport) should be reported first to 12-3. Non-emergency injuries can be handled via the contracting company designated medical provider. If there is any doubt as to the severity of an injury ALWAYS call 1-2-3. Contractors should not call 911 for ambulance service. All ambulance requests should go through the Pfizer Emergency Services by dialing 1-2-3.

3. Emergency Alarms

In most Pfizer buildings, emergencies will be announced via a public address system, or an auto-call alarm (bell) system. In buildings equipped with an auto call system, the emergency auto-call alarms are:

- **FIRE** - 10 fast rings and 3-digit location code
- **TORNADO** - 20 fast rings
- **AREA-WIDE EVACUATION** - Continuous fast ringing
- **BREATHING AIR EMERGENCY** (this refers to the supplied air service for respiratory protection devices) - 7 fast rings
- **FIRST AID EMERGENCY** - 15 rings
- **ALL CLEAR** - Single ring (repeated 4 times)

**NOTE:** Each series of bell alarms will repeat 4 (four) times
4. Fire Extinguishers, Fire Alarm Boxes, Safety Showers & Eye Wash Stations

Posted building emergency maps show the location of fire extinguishers, fire alarm boxes, safety showers and eyewash stations. This equipment is for emergency use only.

Contract firms must provide their own fire extinguishers for welding and burning projects and are not to remove fire extinguishers from Company buildings for non-emergency situations.

5. Evacuation Routes, Assembly Areas and Tornado Shelters

Posted building emergency maps show the location of building evacuation routes, emergency assembly points and tornado shelter locations for the building and area they are working in. When evacuation of a building is necessary due to fire, explosion, or other disaster, all Contractors are expected to know the evacuation routes and follow PA Announcement instructions. Refer to the Emergency Procedures Handbook for additional guidance on evacuations.

In the event of a tornado, Contractors are expected to know the location of the nearest area designated as a tornado shelter. Refer to posted building emergency maps for the location of tornado shelters.

6. Hazard Communication

Pfizer abides by the Michigan “Right-to-Know” regulations and makes information pertaining to the chemical hazards found at their workplace available to all contractors. Specific questions regarding Hazard Communication should be directed your supervision or Pfizer Contact.

Material Safety Data Sheets will be provided to all contractors for any chemical, upon request. Contractors may contact their supervisor, Pfizer Contact, or a Pfizer employee/co-worker to obtain a copy of the MSDS.

Contractors are encouraged to read labels, paying particular attention to information that may be pertinent to their health and safety as well as that of their co-workers. Learn to recognize the various labeling systems used by Pfizer including the National Fire Protection Association’s Hazardous Classification System, and Pfizer’s unique precautionary labeling system.

Pfizer also utilizes warning signs throughout their plants. Examples of those signs include but are not limited to Danger, Caution, Eye Protection Required, Hearing Protection Required, etc. Contractors are expected to be capable of identifying and understanding the meanings for posted warning signs and comply with all requirements and actions stated on those signs.

Hazardous chemicals are found throughout Pfizer. Specific information for individual work areas are available through the Pfizer Contact or the operating unit.

Contractors bringing chemicals onto the premises must maintain MSDS’s on site for those chemicals and provide a copy to the Pfizer Contact. All chemical containers must be properly
labeled. The Administrator will provide a copy to Employee Health.

Contracting Firms are responsible for logging annual chemical usage of regulated items and for removing their unused chemical materials from Pfizer property.

7. Asbestos-Containing Material

Pfizer Kalamazoo sites house many miles of process piping. Asbestos-containing material (ACM) has been identified in portions of the thermal system insulation of the piping. These portions will be identified as follows:

Asbestos Containing Material

Non-ACM (NON Asbestos Containing Material)

Like wise insulation that does not contain asbestos with identified –
Non-ACM (NON Asbestos Containing Material)

Non-thermal system insulation ACM (i.e. ceiling and floor tile, laboratory bench tops, etc) has also been identified and will be marked with labels or stickers.

Contractors who will come in contact with ACM must follow all state and federal regulations pertaining to asbestos. Only properly licensed, trained, qualified individuals will be allowed to disturb any material containing asbestos. Contractors working with asbestos containing material (ACM) must notify their Pfizer Contact prior to beginning work.

PFIZER POLICIES

1. Equipment

Construction Contracting Firms must provide all necessary equipment to perform their job. Each firm must regularly inspect and maintain their equipment in good working condition.

2. Contracting Firm Vehicles

The following rules apply to all Contracting Firm vehicles on Pfizer property:

A. Riding in a vehicle shall be limited to a seat in the cab or to a seat secured to the bed, body, or floor of the vehicle. Seats must be anchored according to federal and state regulatory guidelines. While a vehicle is in motion, personnel within shall not extend any part of their bodies beyond the line of the vehicle bed as defined by its gates, barriers, and/or seat arrangement.
B. Materials being transported which extend beyond the sides or ends of the vehicle shall be properly secured and marked with red flags. All trucks transporting materials on Pfizer property shall be loaded in a secure manner to prevent any material from dropping off the truck onto the roadway.

C. Dump trucks, trailers, waste-hauling units or heavy construction equipment shall not travel with loading devices in an elevated position. Materials shall be placed on site only in locations authorized by the Pfizer Contact.

D. All vehicles or equipment requiring back-up signal devices must be in proper working condition.

E. Fuel tanks on Contracting Firm vehicles or equipment shall not be filled while engine is running or in a hazardous area, such as where welding or other hot work is being performed. On-site fuel tanks require secondary spill containment and must be specifically authorized by the Pfizer Contact and Pfizer Environmental Health & Safety.

3. Contracting Firm Vehicle Permits for PGM Kalamazoo Site access

Red Stickers:
A. This policy covers assignment of a Contractor Commercial Vehicle Permit to allow contract firms limited access and parking within the boundaries of the perimeter fence on Pfizer property at the Portage, Michigan site.

B. The Contractor Commercial Vehicle Permit is intended for use by contractors needing access to construction job sites and work areas where a vehicle is required to perform work, and parking in "Red Permit Required" spaces.

C. The Contractor Commercial Vehicle Permit is not intended for the following:
   1. Pfizer owned vehicles
   2. Delivery vehicles from suppliers
   3. Heavy Equipment operated by Contractors

D. Contractor Commercial Vehicle Permit forms may be obtained from the Kalamazoo Contractor Administration web site at: http://kalamazoocontractoradministration.pfizer.com or by calling KCA at 269.833.7048.

Orange Temporary Pass:
A. Orange vehicle passes will be issued to contractors requiring the use of a commercial vehicle on the Pfizer site for a temporary period of time, usually 1 to 3 consecutive business days.

B. Orange vehicle passes will be issued by Security and may require verification by KCA before being issued to contractors.

4. Dress Codes

All Contractors must conform to the dress code requirements of individual units/areas, as posted at entrances to any of those areas. For area-specific requirements, consult your Pfizer Contact.

All research buildings, either at the Richland Farm or Research and Development Downtown, have dress requirements that are mandated by activities that occur in those buildings. At the Richland Farm site, contractors must not enter animal areas, without prior approval. Some animal housing is inside a building and some is in open feed lot type settings. Regardless of the setting, all contractors must have prior approval to enter these areas.

Areas under construction, or otherwise sealed off from the production or packaging environment, the Pfizer Contact can request a waiver of dress code requirements.

In summary, Contractors shall wear personal protective clothing and footwear that is appropriate for the work location and type of work being performed. Prohibited clothing may include, but is not limited to, canvas shoes, sneakers, slippers, tank tops, and shorts. Shirts and pants are required at all times.

NOTE: In order to protect both people and product, some areas have stricter dress code regulations than those mentioned previously. Examples are the Potent Drug Area or Sterile Manufacturing. All local requirements and procedures must be followed. Pedestrians must be dressed to code requirements to pass through a zone. If in doubt about dress code requirements ...ASK!

ENVIRONMENTAL HEALTH AND SAFETY COMPLIANCE

1. Elevated Work/Fall Protection

Individuals working at Pfizer on any walking/working surface, more than 4 feet above a floor surface that is not adequately protected by guardrails must have proper Fall Protection. Fall protection is generally achieved by using a personal fall arrest system consisting of an anchor point, lanyard and a full body harness. However, there are other methods to achieve adequate fall protection including safety net systems and guardrails. Specific training may be required before working certain Pfizer areas that contain unique fall protection systems, such as the mezzanine area of Drug Products and the trestle area of the API area.

This document is a guide for contract firms doing construction and maintenance work at Pfizer to help identify basic environment, health and safety requirements. This guide will help to identify environment, health, and safety considerations when producing Job Safety Plans prior to bidding on and performing work at Pfizer. It may also be used as a field document to aid in the assessment of environment, health, and safety conditions at construction sites. Contractors shall always comply with company policies, federal, state, local laws, and regulations.

Construction and maintenance sites shall post signs that provide the following information:

- Personal Protective Equipment Required
- Emergency Procedures
- All personnel contacts essential to the project
- Construction Area Hot Work Permit (if applicable)
- Measures to restrict un-authorized personnel are in place

Copies of this manual are available on the KCA Webpage at:

http://kalamazoocontractoradministration.pfizer.com/

3. Radiation

Pfizer is proud to be one of the largest pharmaceutical, fine chemical manufacturing, and medical related research institutions in the world. In our research, we use radioactive material (RAM) and radiation-producing devices. We operate under licenses issued by the U.S. Nuclear Regulatory Commission (NRC) and registrations issued by the Michigan Department of Community Health (MDCH).

Pfizer must comply with all applicable rules and regulations. Violation(s) of these requirements could result in civil penalties (fines) or modification, suspension or revocation of the licenses or registrations. We are required to tell you what NRC and State of Michigan requirements apply to your work and to post Notices of Violation involving radiological working conditions. We do this to assure a safe working environment and to comply with the governmental requirements.

The Radiation Safety Officer (RSO), a trained health physicist, is responsible for the administration of the Radiation Safety Program. Other health physicists at Pfizer are trained in dealing with radioactive materials and the effects of radiation. The Radiation Safety Committee has the
Radiation Safety (RS) provides safety instructions that protect the worker, the public, and the environment. We are committed to provide our customers with services and support in the use of ionizing radiation that meet or exceed all regulatory requirements.

**Radiation and Where It Comes From**

Radiation is a natural energy that has always existed on earth and throughout the galaxy. It is energized particles or waves of pure energy. Radiation can ionize (electronically change), stable atoms. The term “radiation” includes light and radio waves (non-ionizing), but is most often used to mean ionizing radiation. Ionizing radiation is not detected by any of the five senses. Ionizing radiation can cause a change in the chemical composition of many things, including human tissue.

Radiation is received from natural and manufactured sources. The sources of natural or “background” radiation are cosmic rays from outer space and radioactive elements in the earth’s crust. Altitude and the type of rock affect the amount of background radiation we receive. Housing materials, the ground we walk on, plants, animals, and the human body (bones contain radioactive potassium and body tissue contains radioactive carbon) all contain some naturally occurring RAM.

Examples of manmade radiation sources are RAM (i.e., radiolabeled chemicals) used in medicinal research or radiation-producing devices (i.e., x-ray machines) that generate radiation mechanically when the device is ON. Radioactive sources are used in 90% of new drug research and development.

**Access to Radiation Sources**

Our license and state registration covers RAM and radiation-producing devices stored or used at:

Farms Research Complex  Laboratories/Downtown Complex  
Portage Road Manufacturing and Research Complex  

Approved laboratory areas where radiation sources are stored or used are posted to state their presence. These rooms or areas are posted with the international symbol for radiation (purple trifoil on a yellow background) as shown below:

CAUTION  

![Radiation Symbol]

RADIOACTIVE MATERIAL  

To occupy or work in these areas, individuals must attend Laboratory Radiation Worker Training
In order to clean, maintain or modify these areas individuals may be required to attend Ancillary Radiation Worker Training or Laboratory Radiation Worker Training. A Radiation Work Permit may be required.

All material and equipment containing radioactive sources are labeled with the international symbol for radiation:

![CAUTION](image)

**RADIOACTIVE MATERIAL**

All material and equipment containing radioactive sources are handled or operated ONLY by personnel trained in the safe use of RAM.

**Your Rights and Responsibilities**

Specific rights and responsibilities are detailed in State and Federal rules and regulations, and include:

- Your right to receive information on radiation, its possible risks or effects, and precautions and instructions to minimize your exposures.
- Your right to request reports of your radiation exposures (monitored personnel). Most nonusers and visitors are not required to wear dosimetry.
- Your right to choose to decline to enter radiation use areas.
- Your responsibility to observe the provisions for the protection of personnel from radiation and RAM.
- Your responsibility to report to RS any condition which may lead to or cause a violation of applicable licenses and registrations or which may lead to unnecessary exposure to radiation or RAM.
- Your responsibility to maintain your exposures to radiation “As Low As Is Reasonably Achievable (ALARA)”. Your supervisor and RS will provide guidance and assistance but YOU are ultimately responsible.

**Applicable Rules, Regulations, and Licenses Conditions**

State and Federal regulations require that current copies of the following documents be made available to employees for review. These documents are located in the RS office.

**FEDERAL**

- The NRC Type A Broad Scope license, license conditions, all documents incorporated into the
license by reference, and all license amendments.
• Operating procedures applicable to NRC licensed activities.
• Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued by the NRC.

If you have questions or concerns, contact the Pfizer Radiation Safety Officer (RSO).

Call RSO 833-9431 - pager 269-413-0479

4. Bloodborne Pathogens (BBP)

Bloodborne pathogens can be found at Pfizer in research and development, in the animal health buildings and may be used in various testing throughout laboratories on the Kalamazoo Site. Contractors who are required to come in contact with BBP’s should be adequately trained in handling, clean-up and emergency procedures.

Waste created from the use of BBP’s should be considered hazardous and will be identified with the following symbol:

![Biohazard Symbol]

Contractors coming in contact with potentially contaminated fluids should be knowledgeable in the subject and use of “universal precautions” as they are expected to comply with this system of personal protection. “Universal Precautions” as defined by OSHA Standard 1910.1030 subpart b are “an approach to infection control where all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.”

5. Noise Chronic over-exposure to noise can cause hearing loss and other hearing disorders. At Pfizer, areas where noise levels can be expected to exceed 85 decibels (dBA) are considered high noise areas. High noise areas are marked with signs indicating that hearing protection is required. Hearing protection must be made available at the boundaries to all high noise areas. If the work you are doing will introduce a noise source (power tools, generators, etc.) you must protect yourself and alert any one else in the area to do the same. Your Pfizer Contact can help you identify high noise areas. You must inform your Pfizer Contact if the work or equipment you will bring on site will generate a noise hazard.
6. Work Practices

- Areas and roads must be properly barricaded or roped off when hazardous work is in progress. When roads are to be barricaded, contact the Pfizer Contact who will notify Security.
- Sprinkler line shutdowns require a twenty-four (24) hour advance notice to the Pfizer Fire Department. No changes can be made or sprinkler heads covered until the Fire Station has been informed. Arrangements must be made with the Pfizer Contact early enough to allow notification.
- Do not cut into insulated lines with a knife, hacksaw, etc. to remove insulation until a check has been made to see if they are electrical traced lines.
- Insulated lines, mechanical and electrical piping, and ductwork must not be walked on, sat on, or used as a support for scaffolding or ladders.
- Metal ladders are not allowed. All ladders must conform to federal and state guidelines and be visibly identified with the company name.
- Contractors shall not inactivate safety devices such as relief valves, deluge valves, gauge valves, electrical or mechanical interlocks, guards, electrical switches, alarms, etc. unless authorized by the Pfizer Contact or operating unit.
- Contractors shall not remove, reach or climb through, over or under barriers, ropes, tapes, or barricades without proper authorization.

7. Lockout/Tagout (LOTO) Procedures:

Lockout/Tagout (LOTO) procedures are used to control hazardous energy sources during service or maintenance where the unexpected release of energy could cause bodily harm. All contractors performing procedures using LOTO are required to take site-specific LOTO training. Suppliers are required to train their employees on the general principles as required under MIOSHA’s Control of Hazardous Energy Sources standard. Contractors are to contact their supervisor to schedule this course.

Hazardous energy sources come in many forms including:

- Electrical
• Mechanical
• Thermal
• Potential
• Pressure
• Chemical

Key elements on Lockout/Tagout at Pfizer sites:
• Red locks used only for LOTO
• Every person must have personal control of all energy sources
• Lock box must be used for Confined Space and Line Entry permits.
• Tag in field should indicate only the lock box number
• Tag on lock box contains persons name, date, and unit (or company)
• Procedure must be complete before beginning LOTO
• Control lock must be used with Line Entry and Confined Space Entry permits.
• Tags must be secured with the shank of the lock or a plastic cable tie (no string, twist ties, etc.)
• Always test on/off switches to be sure system is de-energized
• All individuals having work duties on that piece of equipment must physical lock-out the equipment

8. Safe Work Permits (SWP)

The Safe Work Permit at Pfizer is a form that has a step by step checklist that ensures applicable jobs are performed safely. All contractors performing procedures using permits are required to take site-specific permit training. The purpose of this procedure is to describe the process by which personnel review and document safety information prior to completing work. The Safe Work Permit is designed to incorporate the permitting requirements for Hot Work, Confined Space Entry, Energy Isolation, Open Pit Entry, Portable Ionizing radiation Sources (X-ray), Line Entry/Line Break, and working with exhaust ducts. The Permit is applicable for all Pfizer colleagues and contractors who work at the Kalamazoo Site. These permits are required for certain job activities, are job specific, must be posted at the job site and cannot be shared with other projects.

All information regarding the Safe Work Permit program may be found in SOP 25922, on the Environmental Health and Safety webpage. Contractors are to contact their supervisor to schedule this course. Pfizer’s Safe Work Permit covers the following types of work:

**Lockout/Tagout** This program is used to control hazardous energy sources when equipment or machines are being serviced, or maintenance is being performed.

**Confined Space Entry** Tanks, vessels, pits, and dikes may all be considered confined spaces. The Confined Space Entry Permit identifies and controls the hazards associated with entering a confined space. A sign posted near the entrance identifies permit Required Confined Spaces. At least 2 people must verify the atmosphere prior to entering any confined space. One of those individuals verifying the atmosphere must be a Pfizer employee.
**Hot Work:** All Welding, cutting, grinding, using electric tools, and other work that has the potential for starting a fire or causing an explosion must have a SWP before work commences.

**Line Entry** An opening in process piping at Pfizer is considered line entry. This will identify any hazards and assure that all measures have been taken to guard against accidental exposure to personnel working on the system.

**Radiation Work** A Radiation Work Permit must be obtained before beginning work on any system containing radioactive material.

**Excavation** Permission via the Excavation Permit is necessary whenever an excavation performed by any type of machine or equipment any dig 4’ or greater. The Requestor, Contract firm(s) and the KCA rep. will meet and review the Pre-Dig Safety Analysis. All excavations will follow MIOSHA Construction Safety Standard Part 9. Ensure that all approval signatures are on the permit before work begins.

A “Qualified Person and Competent Person” in charge of this excavation must be identified before the excavation can occur. Excavation permits will be required to be “Posted” at the job site, along with contact names and phone numbers for the Project Manager, Construction Manager/EMA/CAC, and Qualified Person.

**Five basic rules are to be followed for the SWP:**

1. The permit checklist must be filled out completely. Skipping a step defeats the purpose of the permit and could lead to an accident.

2. All authorized signatures must be obtained. This ensures that those signing the permit agree about the type of work to be done and are satisfied that the area is safe.

3. The permit must be posted at the job site so that it can be easily seen.

4. Each safety permit applies to one job being performed at a specific location at a defined time by certain workers. This means that permits CANNOT be shared by Contracting Firms and moved from job to job. If work needs to be done on another system, or on a different day, another permit needs to be obtained.

5. The permit must be returned to the office where it was issued upon completion of the job. It is very important that all people involved in the permit process know when the job is finished. Safety permits are reviewed regularly and revised as necessary. Ask your Pfizer
9. Personal Protective Equipment

Hard hats are required in all construction areas on Pfizer property. To reduce the risk of electric shock, metal hard hats are NOT allowed under any circumstances.

Appropriate personal protective equipment is required for work in many posted areas as well as for certain activities. Adherence to posted personal protective equipment requirements is strictly enforced. Failure to comply is grounds for dismissal from company property.

ANSI-approved safety glasses with side shields are the minimum protection required in all construction, production, laboratory and posted areas. Use of tinted lenses inside buildings is prohibited. In addition, goggles, face shields, or other approved face and eye protection shall be used where a hazard exists due to flying objects, particles, harmful contacts (i.e. chemicals), and other potentially hazardous exposures. All processing areas require safety glasses with side shields. Goggles must be worn when performing tasks that present splash hazards such as, but not limited to, hose connection/disconnection, open sampling of liquids, or line/equipment opening. In addition, goggles AND a face shield (or a combination device of both) are required for any processing task involving the open handling of corrosives.

For individuals working in Kalamazoo Drug Products (KDP) consult the current version of Standard Operating Procedure (SOP) 12180 for specific dress code requirements.

10. Respiratory Protection

Your Pfizer Contact will identify whether respiratory hazards may be associated with the work areas you will need to access. If you need to use respiratory protection to do your job you must have medical clearance to use respiratory protection and training on its use. In addition, certain forms of respiratory protection will require fit testing. In most cases, your employer will be required to provide the respirator, medical clearance, training and fit testing. If you need to use the Pfizer breathing air system, your Pfizer Contact may provide a compatible respirator and will arrange for training specific to its use. You must inform your Pfizer Contact if the work or equipment you will bring on site will generate a respiratory hazard. If the work you are doing will introduce a respiratory hazard you must protect yourself and alert any one else in the area to do the same.

11. Waste Disposal

The Pfizer Contact is responsible for the proper disposal of hazardous and non-hazardous liquid and solid wastes generated as a result of contractor activities. Therefore your Pfizer Contact must be consulted prior to disposal in order to ensure compliance with Pfizer disposal procedures and applicable regulations. In addition, consultation with the Pfizer
Environmental Compliance Unit is required to determine proper waste characterization and disposal. All hazardous material that is to be disposed of must have a label that contains the name of the material and placed in a container that is appropriate for the type of material that is to be disposed.

If excavation of soils is to be performed, contractors must contact the Pfizer Contact to obtain a signed Excavation Tracking Log Authorization Form. This will ensure that excavated soils are disposed of in a cost-effective and appropriate manner.

12. Chemical Exposure

If a contractor comes in contact with a chemical, they should always immediately go to and use the nearest safety shower as an initial first aid mechanism, if the material burns or irritates the skin, and especially if the material is water reactive. Safety showers are designed to deliver large volumes of water that are beneficial in removing as much of the chemical as fast as possible, which may minimize injuries. Remember to always call 1-2-3- and notify your supervisor of any injury of this type.

NOTE: This test questions describes the API Building entrance and exit procedure. This procedure has been replaced by a new policy governing access to those buildings. When to test is updated, this test question will also be replaced. To help everyone get 100% on the test, the answer to this question is “D” - All of the above.